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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

)
HEALTH SCIENCE FUNDING, LLC,) HON. CLAIRE C. CECCHI
)
Plaintiff,) Civil Action No.
v.) 2:13-cv-03663-CCC-JAD
)
THE UNITED STATES FOOD & DRUG)
ADMINISTRATION and) **REPLY MEMORANDUM IN**
MARGARET A. HAMBURG, in her official) **SUPPORT OF DEFENDANTS'**
capacity as Commissioner of the FDA,) **MOTION TO DISMISS**
)
Defendants.) Motion Date: Aug. 19, 2013

)

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INTRODUCTION

Plaintiff wants to market its DHEA product, Prastera, as a medical food for lupus patients, free from the Food and Drug Administration’s (“FDA”) drug premarket approval requirements and free from the possibility that the agency might someday disagree about the regulatory status of Prastera and take enforcement action. FDA has taken no action toward plaintiff other than agreeing to a courtesy meeting. Because there is no final agency action and no injury, plaintiff lacks standing and its claims are not ripe. Plaintiff misconstrues the relevant case law and FDA’s arguments in an attempt to manufacture standing and ripeness, but it has failed to carry its burden to establish that this Court has jurisdiction to hear its claims. Nor can plaintiff overcome controlling authority foreclosing the preenforcement judicial review it seeks. Finally, plaintiff has failed to state any valid claim under the Administrative Procedure Act (“APA”) and failed to state a claim on the merits for which relief can be granted. For these reasons and those previously stated, this Court should dismiss the complaint with prejudice.

A. Plaintiff’s Complaint Should be Dismissed Due to a Lack of Standing

Plaintiff claims that manufacturers have standing to sue any time that FDA does not have a process for premarketing review and it is possible that FDA could bring an enforcement action. *See* Pl.’s Opp. at 3. Plaintiff relies on *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), but the critically different facts in *Abbott* do not support plaintiff’s overly broad views. In *Abbott*, plaintiffs had standing to challenge FDA’s *promulgation of a final rule*, in part because:

[T]he regulation is directed at them in particular; it requires them to make significant changes in their everyday business practices; [and] if they fail to observe the Commissioner’s rule they are quite clearly exposed to the imposition of strong sanctions.

Abbott at 154. By contrast, FDA here has promulgated no rule and directed no final regulatory or enforcement action towards plaintiff. Rather, plaintiff complains of FDA *inaction* (because

FDA does not conduct premarket reviews for medical foods), and speculative future actions, but can point to no present action or injury. Plaintiff's fear is not "concrete in the qualitative and temporal sense;" nor is it "distinct and palpable" and "actual or imminent." *See Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990).

Nor does plaintiff's bare allegation that FDA officials threatened enforcement constitute an injury. Any such informal statement made at meeting, even if true, does not confer standing. *See* 21 C.F.R. § 10.85(k). Plaintiff asserts, without any basis, that the alleged threats reflected the "agency's formal position, taken at the highest level and after consultation with legal counsel." Pl.'s Opp. at 4. FDA officials agreed to meet with plaintiff as a courtesy, but they did not undertake a formal review of all of plaintiff's information or issue a Warning Letter. *A fortiori*, because FDA Warning Letters do not even constitute final agency action,¹ the alleged verbal statements made to plaintiff do not qualify as final agency action. Indeed, plaintiff's marketing of its product without FDA interference nearly six months after that meeting undercuts its claim of injury.

Plaintiff also makes the curious assertion that—because FDA does not do "pre-enforcement review"—"its Warning Letters are by definition baseless." Pl.'s Opp. at 6. Plaintiff confuses "pre-enforcement review" with premarketing review. FDA lacks statutory authority to conduct premarketing review of medical foods, and does not conduct such reviews. FDA has the authority, however, to enforce violations of the act. 21 U.S.C. § 337(a). Its actions initiated to achieve compliance (such as issuing Warning Letters) are not baseless, but conducted after reviewing available evidence. Thus, FDA *does* conduct "pre-enforcement review" when it

¹ See, e.g., *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944-45 (D.C. Cir. 2012); *Mobil Expl. & Prod. U.S., Inc. v. Dep't of Interior*, 180 F.3d 1192, 1198-99 (10th Cir. 1999); *Dietary Suppl. Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992).

undertakes an enforcement action, but its deliberations before any such enforcement action are not reviewable. *See Section C, infra.* Here, FDA has neither completed any pre-enforcement review for plaintiff's product, nor taken any enforcement action against plaintiff.

Plaintiff appears to challenge the long line of authorities holding that FDA Warning Letters are not final agency action, observing that other manufacturers who received Warning Letters related to medical foods complied with FDA's request.² But this is exactly what FDA Warning Letters are designed to do: achieve voluntary compliance without initiating action in court. FDA did not take any enforcement action against any of those companies. Evidence of voluntary compliance does not elevate the status of the Warning Letters to final agency action.³

Plaintiff also submitted a letter from a physician stating that a Warning Letter would change his prescribing habits, and that he "would only prescribe a drug that had an FDA warning in place under very special circumstances." Dkt. No. 14. This letter is irrelevant because FDA has not sent plaintiff a Warning Letter. Moreover, the physician refers to a "drug," but plaintiff wishes to market its product as a medical food under a unique provision of federal law. It is not clear that the physician would even prescribe plaintiff's product at all if it were marketed as a medical food instead of a drug. This self-serving letter offered outside the pleadings does not advance plaintiff's claim of standing.

² Plaintiff also incorrectly asserts that FDA's administrative evaluation was ongoing in each of these cases. Pl.'s Opp. at 6. In *Cody Laboratories, Inc.*, for example, the Court refused to adjudicate the issue whether plaintiffs' drugs were grandfathered in the absence of an actual enforcement action and there is no indication, at the time of the litigation, that there was ongoing administrative review of that question. *See Cody Labs., Inc. v. Sebelius*, No. 10-147, 2010 U.S. Dist. LEXIS 80118, at *10 (D. Wyo. July 26, 2010), *aff'd*, 446 Fed. Appx. 964 (10th Cir. 2011).

³ Plaintiff cites *Columbia Broadcasting System v. United States*, 316 U.S. 407 (1942), for the proposition that an agency policy statement that coerced compliance was ripe for review even without formal enforcement. Pl.'s Opp. at 10-11. That case, however, concerned a challenge to a final regulation with legal consequences, 316 U.S. at 417, and is inapposite here.

B. Plaintiff's Claims Are Not Ripe

Plaintiff argues that its claim is fit for review because it raises purely legal, and not scientific, issues and that no further factual development is necessary. Pl.'s Opp. at 9, 11. Thus, plaintiff pointedly misconstrues, or does not understand, the factual issues that FDA identified in its brief. First, FDA has not considered whether DHEA is allowed for use in medical foods. *See* 21 U.S.C. § 348(a).⁴ Plaintiff apparently believes that the requirements set forth in 21 U.S.C. § 348 only apply to the other ingredients in its product such as olive oil and gelatin, and expresses frustration that FDA is “unable to figure out whether olive oil is legal.” Pl.'s Opp. at 12. But FDA referred to the status of DHEA in its brief, not the status of other additional ingredients. Defs.' Br. at 8. Plaintiff argues that the food additive definition is somehow irrelevant for DHEA because plaintiff does not use its DHEA as an artificial flavoring and food coloring, citing a food additive definition from Wikipedia. Pl.'s Opp. at 23. But Wikipedia does not trump the legal requirements related to ingredients used in medical foods.

Second, FDA pointed out that plaintiff apparently co-packages its DHEA product with either ibuprofen tablets (in the labeling presented to this Court) or anti-acne topical gel (in the labeling on its website), and that this co-packaging raises the question of whether plaintiff's product is an unapproved new drug. Defs.' Br. at 15. Plaintiff asserts that this unanswered question means that FDA is somehow unable to interpret the medical food statute. Pl.'s Opp. at 23. Nonsense. FDA is fully capable of interpreting the relevant statutes and applying them to a

⁴ An ingredient that is added to a medical food must be safe and suitable and comply with all applicable statutory and regulatory provisions. Any ingredient added to a medical food should be (1) a food additive used in accordance with FDA's food additive regulations (*see* 21 C.F.R. pt. 172); (2) a color additive used in accordance with the color additive regulations (*see* 21 C.F.R. pts. 73 and 74); (3) a substance that is generally recognized, by qualified experts, to be safe under the conditions of its intended use (Generally Recognized As Safe, GRAS) (*see* 21 C.F.R. § 170.30 and 21 U.S.C. § 321(s)); or (4) a substance that is authorized by a prior sanction issued by FDA (*see* 21 C.F.R. § 170.3(l)).

specific set of facts at an appropriate time, such as in the course of considering enforcement action. As described above, FDA has not yet considered this question in the context of Prastera.

Plaintiff's confusion regarding premarketing versus pre-enforcement review of medical foods leads it to the incorrect conclusion that FDA lacks the resources to perform scientific evaluations at all and this Court should perform this function instead. *See* Pl.'s Opp. at 11-12. Plaintiff also argues that its claim is purely legal because of its erroneous assertion that physicians, not FDA, determine whether a product is a medical food. *Id.* at 18. But, for all of the reasons stated in FDA's opening memorandum, FDA has the authority and responsibility to construe the relevant statutory provisions. Defs.' Br. at 23-25. The statute requires a determination whether a condition needs "specific dietary management" and whether it has "distinctive nutritional requirements." 21 U.S.C. § 360ee(b)(3). These are scientific, not legal, determinations committed to FDA.

Fitness for review also turns on the finality of the agency action challenged. Plaintiff concedes that FDA has taken no final agency action, but argues that final agency action is not necessary, citing *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986). Pl.'s Opp. at 9-10. In that case, the D.C. Circuit held that a manufacturer's claim against EPA was ripe in the absence of an enforcement action because the EPA had expressed a final view in letters to the manufacturer that EPA had authority to bring an enforcement action to impose labeling changes without following a statutorily-prescribed cancellation proceeding. *Id.* at 435. The court noted that "fitness for review encompasses several factors, including whether the issue presented is a purely legal one, whether consideration of that issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Id.* Because EPA had definitively stated its position on a purely legal issue of statutory construction, *i.e.*, that it could impose labeling

changes on registered pesticides without following the cancellation process, the court held that the plaintiff's claims were ripe. Notably, the court acknowledged that if the manufacturer had sought a "declaratory judgment that the available scientific evidence does not warrant a misbranding action," and challenged the merits of the agency's decision, the claims would not have been ripe. *Id.* at 437 n.8.

By contrast, the controlling merits issue here is whether Prastera is a medical food. Resolution of that issue would require this Court to decide undeveloped factual issues concerning whether lupus requires "specific dietary management" or has "distinctive nutritional requirements," as well as whether DHEA satisfies the requirements for ingredients in 21 U.S.C. § 348(a), and whether plaintiff's apparent co-packaging renders its product a new drug under 21 U.S.C. § 321(p)—all without the benefit of having FDA first make those determinations and develop a record for this Court's review. Plaintiff's request for preenforcement review would "be a means of turning prosecutor into defendant before adjudication concludes," *FTC v. Standard Oil. Co. of Cal.*, 449 U.S. 232, 242 (1980), and is not ripe for this Court's review.

Plaintiff claims that it has satisfied the "hardship" prong of the ripeness test because "access to Plaintiff's product is impaired by FDA's threat of baseless enforcement action," "FDA's Medical Food Warning Letters poison product reputation irreparably," and "women with lupus will be harmed by reduced access to, or complete denial of, a beneficial product." Pl.'s Opp. at 9-10. But FDA has not taken any action to restrict plaintiff's marketing, such as issuing a Warning Letter, which (even if it had) would not impose any requirements on plaintiff. In the absence of any actual hardship, plaintiff's claims are not ripe.

Much of plaintiff's alleged hardship appears to result from plaintiff's own choice to market its product as a medical food, for which no premarketing approval pathway exists. Pl.'s

Opp. at 12. This pathway necessarily results in some degree of regulatory uncertainty unless and until FDA takes an enforcement action. If plaintiff had wanted greater regulatory certainty, plaintiff could have sought approval of its product as a drug to treat lupus, as a previous sponsor has tried to do. *See* Defs.' Br. at 9. But because formal procedures for rendering a premarket decision about plaintiff's product do not exist, and FDA may never bring an enforcement action, plaintiff's claim of hardship "is not ripe for adjudication" because "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *See Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted).

C. FDA Enforcement Action May Not Be Enjoined

Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950), forecloses challenges to future enforcement actions. Plaintiff argues that *Ewing* only applies if "the agency is in the midst of an on-going pre-enforcement evidentiary review." Pl.'s Opp. at 13. But for all of the reasons stated previously in Section A, *supra*, plaintiff has confused premarketing approval with preenforcement review. FDA does not conduct premarketing reviews for medical foods. But as with any product under FDA's jurisdiction, it is always possible that FDA may take enforcement action if that product is violative. Under *Ewing*, any such enforcement may not be enjoined.⁵

D. Plaintiff Has Failed To State a Claim Upon Which Relief Can Be Granted

Even if this Court had jurisdiction to hear plaintiff's claim, plaintiff has still failed to state a claim that Prastera is a medical food, even assuming that plaintiff's factual allegations are correct. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007).

⁵ For similar reasons, plaintiff also fails to state a valid claim under the APA. Judicial review under the APA requires that the agency has taken final action. *See* 5 U.S.C. § 704. Plaintiff incorrectly assumes that FDA's "preenforcement decision making process is consummated" because FDA does not perform premarketing reviews for medical foods. Pl.'s Opp. at 14. FDA has not taken any final agency action towards plaintiff.

1. FDA's Regulatory Definition of Medical Food Excludes Prastera

FDA has clarified by regulation that a medical food may only be intended for a disease or condition with nutrient requirements that cannot be met through the consumption of conventional foods (which may include dietary supplements). *See* 21 C.F.R. § 101.9(j)(8)(ii) (“the dietary management . . . cannot be achieved by the modification of the normal diet alone”). Plaintiff does not dispute that DHEA is widely available as a dietary supplement, and that Prastera does not qualify as a medical food under the criteria set forth in FDA’s regulation.

Rather, plaintiff argues that the regulation is not on point, and that it conflicts with the statute. Pl.’s Opp. at 17. Plaintiff is wrong. FDA is authorized to promulgate regulations, *see* 21 U.S.C. § 371(a), and has done so here in the context of nutrition labeling. FDA regularly interprets ambiguous statutory terms (such as “distinctive nutritional requirements”) in regulations. Such agency interpretations must be upheld if they are based on a permissible construction of the statute. *See In re Avandia Mktg.*, 685 F.3d 353, 367 (3d Cir. 2012) (citing *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984)).

FDA’s interpretation of “distinctive nutritional requirements” as those that cannot be met by modification of the normal diet is a straightforward application of the statute and is clearly permissible. The regulation properly implements the entire regulatory scheme under FDA’s purview, including drugs, medical foods, and dietary supplements. Plaintiff’s contrary broad view of the statutory definition of medical foods would allow manufacturers to effectively market their products as drugs without providing any evidence that their products were safe or effective.⁶

⁶ Plaintiff also argues that FDA’s regulatory definition could produce arbitrary results because it depends on the availability of other products, Pl.’s Opp. at 18, but plaintiff does not dispute that DHEA products are in fact widely available.

Plaintiff also contends that the regulation only exempts “certain kinds of medical foods” from nutritional labeling requirements. Pl.’s Opp. at 17. But plaintiff’s view that only certain medical foods are exempt under the regulation does not comport with the statute, which exempts all medical foods (appropriately classified) from those nutritional labeling requirements. *See* 21 U.S.C. § 343(q)(5)(A)(iv). FDA has clarified which products are subject to that exemption in 21 C.F.R. § 101.9(j)(8). FDA reasonably applies that same definition across the board when determining whether or not a product is a medical food.

2. FDA Decides Which Products Qualify As Medical Foods

Plaintiff also argues that physicians, not FDA, determine what products are medical foods. Plaintiff argues that FDA previously agreed with this approach and has now “abruptly change[d] its position,” quoting from FDA’s 1996 Advanced Notice of Proposed Rulemaking: “The physician determines that the medical food is necessary to the patient’s overall medical care.” *See* Pl.’s Opp. at 19 (quoting 61 Fed. Reg. 60661, 60668 col. 2 (Nov. 29, 1996)). But that statement does not suggest that the physician determines that the product is a medical food, only that the physician makes a determination that the product is necessary to the overall care of a specific patient. Elsewhere in that same notice, FDA expressed “[t]he need for physicians and patients to have confidence that any claim that a product is a medical food formulated for the specific dietary management of a disease or condition requires that a strong standard of substantiation be in place.” 61 Fed. Reg. 60666-67. Physicians are not regulators and have no delegated authority to determine whether individual products are medical foods. Rather, physicians rely on substantiated labeling claims when providing specific care to patients.

FDA’s interpretation does not conflict with the plain language of the statute, as plaintiff asserts. Pl.’s Opp. at 19. Under the statute, a medical food “is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on

recognized scientific principles, are established by medical evaluation.” 21 U.S.C. § 360ee(b)(3). In particular, whether a disease or condition requires “specific dietary management,” or has “distinctive nutritional requirements” is a general question about the disease or condition that FDA is in the best position to answer after reviewing available evidence such as clinical trial data or literature reports. The patient-specific medical evaluation confirms that the product is appropriate for that patient, but such an individualized determination cannot substitute for the agency’s regulatory decision about whether the product is a medical food in the first instance. As to that question, FDA unquestionably has the authority and responsibility to construe and apply its statute. *See, e.g.*, 21 U.S.C. § 371(a) (granting FDA general authority to issue binding, substantive regulations); *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967 (2005) (deferring to agency’s interpretation of an ambiguous statute, noting that such interpretation “involves difficult policy choices that agencies are better equipped to make than courts”).⁷

Plaintiff’s physician-as-regulator interpretation would increase the uncertainty about the regulatory status of plaintiff’s product because different physicians could come to different conclusions. Plaintiff argues that its approach is not, in fact, a free-for-all, and that FDA’s authority to assure product quality (presumably through good manufacturing requirements at 21 C.F.R. pt. 110) mitigates that concern. Pl.’s Opp. at 19. But that one aspect of FDA’s

⁷ Plaintiff argues unpersuasively that because FDA does not “vet” medical foods or have the resources to undertake premarket review, FDA’s interpretation would read such products out of the Orphan Drug Act entirely. Pl.’s Opp. at 19. But many products are marketed as medical foods without FDA interference. *See* FDA Compliance Program Guidance Manual 7321.002 (Sept. 30, 2008), *available at* <http://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073339.pdf> (“Currently, marketed medical foods with a wide variety of claims are used extensively as a life support modality in the management of the critically ill and elderly.”). Rather than impede such marketing, the lack of premarketing review generally opens the door to greater marketing of such products, subject to later possible enforcement.

authority does not sufficiently address whether a product qualifies as a medical food in the first instance. FDA's decision on that question protects patients from unsubstantiated labeling claims and gives physicians assurance that they can rely on the labeling when providing patient care.⁸

Plaintiff also argues that physicians regularly evaluate medical claims from manufacturers and are well-equipped to determine whether a disease or condition has distinctive nutritional requirements. Pl.'s Opp. at 21. While physicians may occasionally evaluate such claims in promotional brochures, they generally do not conduct such assessments for actual product labeling. For drug product labeling, for example, FDA reviews the scientific evidence relevant to any labeling claims and must deny approval to a drug if it finds that "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(5). And although FDA does not undertake premarket review of medical foods, FDA may still take regulatory action against a product that does not qualify as a medical food. This authority assures that physicians can rely on labeling claims for medical foods:

A physician relies on the claims made for medical foods on their labels and in their labeling as a significant factor in deciding whether to use a particular medical food in the clinical management of a patient. Thus, it is essential that the claims made for such a product present an accurate interpretation of the scientific evidence concerning the usefulness of that product or specific formulation.

61 Fed. Reg. 60671.

Finally, plaintiff fails to even address FDA's point that medical foods do not technically

⁸ Plaintiff wrongly asserts that FDA is incompetent to decide whether products are medical foods because of recent issues with compounded drugs. Pl.'s Opp. at 19-20. Plaintiff argues that the Supreme Court granted FDA regulatory responsibility for compounded drugs in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), and that FDA has not adequately protected patients. *Id.* But in *Western States*, the Supreme Court struck down prohibitions on advertising compounded drugs; it did not address FDA's authority to regulate other aspects of such drugs. 535 U.S. at 376-77. More to the point, any regulatory uncertainties concerning compounding are irrelevant to FDA's regulatory authority to determine whether a product is a medical food.

require a prescription under 21 U.S.C. § 353(b) and 21 C.F.R. § 201.100, Defs.’ Br. at 24 n.19, but instead asserts that its product’s labeling indicates that it does require a prescription. Pl.’s Opp. at 21. Such a statement, however, does not create an actual requirement for a prescription where none exists under the statute or regulation.

CONCLUSION

For the foregoing reasons, plaintiff’s complaint should be dismissed with prejudice.

Dated: August 12, 2013

Respectfully submitted,

/s/ Roger Gural

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee in the United States Department of Justice and is a person of such age and discretion as to be competent to serve papers.

On this date the undersigned caused to be sent via CM/ECF, a copy of REPLY
MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS, addressed to:

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I declare under penalty of perjury that the foregoing is true and accurate to the best of my knowledge, information and belief.

DATED: August 12, 2013

s/ Roger Gural

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